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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,504	05/18/2005	Ira Sanders	SAND3.0-003PCT/US	9381
47375	7590	09/12/2007	EXAMINER	
OMRI M. BEHR 325 PIERSON AVENUE EDISON, NJ 08837-3123			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,504	Applicant(s) SANDERS, IRA	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Please note that the Patent Examiner of your application in the PTO has changed. All communications should be directed to Rodney P. Swartz, Ph.D., Primary Examiner, Art Unit 1645, whose telephone number is (571)272-0865.

Applicant's Response to Restriction Requirement, received 2 July 2007, is acknowledged. Applicant elects, with traverse, Invention I, claims 1-20, drawn to method of blocking/reducing physiological reactions due to IgE cross-linking by allergan. Applicant's traversal is on the grounds that: 1) neither cited reference appears to mention IgE, and 2) the inventions are linked by the common concept relating to IgE.

After review of the instant case, the current examiner vacates the Restriction Requirement.

2. Claims 1-24 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:
Page 2, line 25, "percent¹" appears to refer to a footnote, but there are no footnotes;
line 29, delete the " following 1998.
Page 4, line 10, delete one of the commas following "skin"; line 29, what is meant by "01 02 agonists"?
Page 5, line 6, what is meant by "systematically/systemically"?
Page 6, line 16, "humunol" should be "Immunol."; line 20, what is meant by "honiopentamer"?
Page 7, line 11, insert comma between "enzymes" "and"; line 26, insert comma between "nose" and "sneezing".

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Page 10, line 12, "method" should be "methods" and "asre" should be "are".

Page 11, line 1, "ion" should be "in"; line 14, "infectious" should be "infections"; insert "at" between "are" and "risk".

Page 13, should "TnT" be "TeNT"; line 26, "discussed is" should be "discussed in".

Page 14, line 20, should "BT" be "BoNT"?

Page 16, line 10, delete the parenthesis at the end of "laboratories"; line 13, "as is it" should be "as is"; line 22, "invovled" should be "involved".

Page 17, line 4, "sapiens, .to" should be "sapiens, to"; line 16, is "Metabologics" the correct spelling of the company name?

Page 18, line 30, something is missing in "space. tympanic".

Page 19, line 8, "sp" should be "sp."; line 22, delete the parenthesis following "dermatitis"; line 28, delete the parentheses following "eosinophils".

Page 21, line 4, "BoNT topically" should be "BoNT were topically".

Page 22, line 14, what is meant by "patient is of 0.5 cc"?

Page 24, line 14, delete "and is absorbed"; line 26, "coacoa" should be "cocoa".

Appropriate correction is required.

Claim Objections

4. Claim 17 is objected to because of the following informality: line 1, "adminstered" should be "administered". Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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6. Claims 21-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-23 provide for the use of a neurotoxin (CnT), but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 3, 4, 5, 21, and 24 recite that a neurotoxin is "derived" from Clostridia or "derived" from serotypes. The specification does not define what the metes and bounds of what constitutes a "derivation" as claimed. Therefore, the claims are indefinite. Claims 2, 6-20, 22, and 23 depend from these claims, but do not clarify the issue.

10. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is an improper listing of a Markush group, i.e., there is no alternative language. The ending of the group should be "beratti, and, C. tetani". Claims 4 and 5 depend from claim 3, but do not clarify the issue.

11. Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite either a mist containing "same" or suppository containing "same". It is unclear what is meant by "same". It is suggested that in claim 12, the phrase be "mist containing said CnT" and in claim 14, the phrase be "suppository containing said CnT"

12. Claims 15 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims list a group of conditions or symptoms. However, the placement of two "ands" make the listing unclear concerning what is the actual grouping terms.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaari et al (*Otolaryngol. Head Neck Surg.*, 112:566-571, 1995).

Claims 21-23 are drawn to the use of a neurotoxin from *Clostridia* sp. For the production of a medicament. The recitation of the intended use of the medicament carries no patentable weight. The only step/reagent listed in the claims is "a neurotoxin from *Clostridia* sp.". Shaari et al teach a method of making a medicament comprising a neurotoxin from a *Clostridia* sp. (Abstract; section **Experimental**, page 567-568).

Claim 24 is drawn to a medicament comprising a neurotoxin derived from *Clostridia* species and a pharmacologically acceptable carrier. The remainder of the claim is drawn to intended use, which carries no patentable weight. Shaari et al teach the product, i.e., a medicament comprising a neurotoxin derived from *Clostridia* species and a pharmacologically acceptable carrier, i.e, normal saline (Abstract; section **Experimental**, lines 7-13, page 567).

Conclusion

15. No claims are allowed.

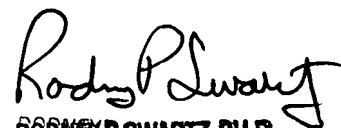
16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

Art Unit 1645

September 10, 2007